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10/776,013	02/09/2004	Jean-Marc Roch	1600.24	2028

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EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	**PAPER NUMBER**
1649	

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/776,013	ROCH ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *6-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 February 2004* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/6/5*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in the reply filed on January 20, 2006 is acknowledged. The traversal is on the ground(s) that all claims "pertain to, or make use of, a biological activity of the same protein; namely, FAK2" (bottom at page 6 of the Response). This is not found persuasive because an application may properly be required to be restricted to one of two or more claimed inventions if they are able to support separate patents and they are either independent (MPEP § 806.04 - § 806.04 (j)) or distinct (MPEP § 806.05 - § 806.05 (i)). The Examiner has shown that the Groups I to VI are independent or distinct for the reasons in the previous Office action (see Paper mailed on December 20, 2005). Furthermore, MPEP § 803 provides that the separate classification (i.e., class and subclass) of distinct inventions is sufficient to establish a *prima facie* case that the search and examination of the plural inventions would impose a serious burden upon the Examiner; such separate classification was set forth in the Office action mailed on December 20, 2005.

The requirement is still deemed proper and is therefore made FINAL.

Claims 6-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on January 20, 2006.

Claims 1-5 and 20 are under examination in the instant office action.

Sequence compliance

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821 (a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. § 1.821 through 1.825. Specifically, no sequence identification has been provided for the nucleic acid sequences presented in Figures 1 to 59 of the instant specification. In case these sequences are new, Applicant needs to provide a substitute computer readable form (CRF) copy of a "Sequence Listing" which includes all of the sequences that are present in the instant application and encompassed by these rules, a substitute paper copy of that "Sequence Listing", an amendment directing the entry of that paper copy into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. § 1.821 (e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d). The instant specification will also need to be amended so that it complies with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. See M.P.E.P. 2422.04.

Claim Objections

3. Claim 3 is objected to because of the following informalities: "in a cells" should be "in cells", perhaps. Appropriate correction is required.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1-5 and 20 are rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility. The instant application has provided description of focal adhesion kinase 2 (FAK2) and binding experiments involving FAK2. The instant application does not disclose specific significance of biological activity of FAK2 with respect to treatment of Alzheimer's disease.

It is clear from the instant application that the instant "invention is based on the discovery of novel interactions between the pairs of proteins", specifically FAK2 and other various proteins, within two-hybrid binding assays (page 3 of the instant specification and also Tables 26, 27 and 54, for example). FAK2 protein was used in the protein-protein binding assays because of its potential association with neurodegenerative conditions of the brain. There is little doubt that, after complete characterization, FAK2 and its naturally occurring binding partner proteins may be found to have a specific and substantial credible utility in methods of treatment of Alzheimer's disease, as currently claimed. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which the court expressed the opinion that all chemical compounds are "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediate obvious or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process

> is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion".

The instant claims are drawn to a method of selecting agents that are potentially useful for the treatment of Alzheimer's disease (AD) by identifying test agents that alter the biological activity of FAK2, emphasis added. The instant specification describes focal adhesion kinase 2 (FAK2) as a member of a "special subfamily of cytoplasmic protein tyrosine kinases (PTKs)", which is "is expressed at its highest levels in brain, at medium levels in kidney, lung, and thymus [...]. In the brain, FAK2 is found at its highest levels in the hippocampus and the amygdala". It is further stated in the instant specification that "FAK2 is thought to participate in signal transduction mechanisms elicited by cell-to-cell contacts [...] involved in the calcium-induced regulation of ion channels, and it is activated by the elevation of intracellular calcium concentration following the activation of G protein-coupled receptors (GPCR)" (bottom at page 72 of the instants specification). The specification also discloses "that a fragment of FAK comprising amino acid residues 724-1052 interacted with a portion of casein kinase II, alpha 2 (CSNK2A2) comprising amino acid residues 264-351. [...], there is a large body of evidence that phosphorylation cascades are deeply altered in the brains of AD patients" (bottom at page 77). The specification asserts that *in vitro* screening assays for test compounds that modulate the biological activity of FAK2 are useful "as a means for screening for compounds [for] the treatment of neurological disorders, ailments and diseases, including mild cognitive impairment, depression, schizophrenia, obsessive-compulsive disorder, bipolar disorder, and neurodegenerative diseases and disorders and motor neuron disorders such as Alzheimer's

disease, Parkinson's disease, dementia with Lewy bodies" (see pages 152-153 for the list of pathological conditions asserted to be treated by agents identified as affecting biological activity of FAK2).

In the absence of knowledge of the specific biological significance of FAK2 with respect to Alzheimer's disease pathology, there is no immediately obvious patentable use for the claimed method of selecting agents that are capable of affecting biological activity of FAK2, which are asserted to be potentially useful for the treatment of Alzheimer's disease. The instant specification fails to provide any evidence or sound scientific reasoning that would support a conclusion that the FAK2 is specifically associated with Alzheimer's disease or any other "neurological disorders, ailments and diseases". Characterization of a binding assay involving a protein (FAK2), which is potentially associated with neurodegenerative processes of the brain, is clearly not sufficient to establish the utility of a method for selecting pharmacological agents to treat a neurodegenerative disorder, including Alzheimer's disease.

§101 requires a utility that is "substantial", i.e., one that provides a specific benefit in currently available form (*Brenner*, 383, U.S. at 534-35, 148 USPQ at 695). *Brenner's* standard has been interpreted to mean that "vague, general disclosures or arguments of "useful in research" or "useful as building blocks of value to the researcher" would not satisfy §101. See *Kirk*, 376 F. 2d at 945 153 USPQ at 55 (interpreting *Brenner*).

In the absence of the specific biological significance of changes in activity of FAK2 with respect to Alzheimer's disease, the information that a test agent is capable to change that activity is nothing more than an invitation to further research. The record does not support Applicant's claim that an agent that is capable to affect activity of FAK2 would be beneficial in treatment of

Alzheimer's disease. The instant specification, as filed, provides no such information or guidance on how such information would allow those skilled in the art to use the test agents identified by the claimed method in a specific substantial way.

Thus, the record does not support Applicant's position that the identification of a test agent as being capable to affect the activity of FAK2 would have suggested its specific use for the treatment of Alzheimer's disease, or any other basis for patentable utility, to a person skilled in the art at the time the application was filed. Since the instant specification does not disclose a credible "real world" use for the claimed method in their currently available form, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-5 and 20 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Further, Applicant is advised that Claims 1-5 and 20 are single means claims in that they recite a method step as "wherein a [any] difference indicates the test agent is potentially useful for the treatment of Alzheimer's disease". MPEP 2164.08(a) defines a single means claim as a

claim which covered every conceivable means for achieving the stated purpose when the specification disclosed at most only those means known to the inventor. This type of claim was held to be nonenabling for the scope of the claim in *In re Hyatt* , 708 F.2d 712, 218 USPQ 195 (Fed. Cir. 1983) because the specification disclosed at most only those means known to the inventor. In the instant case, one skilled in the art readily appreciates that any agent, when contacted with FAK2, would either inhibit or activate the biological activity of FAK2. When claims depend on a recited property, which in the instant case is the ability to non-specifically affect activity of FAK2, a fact situation comparable to *Hyatt* is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor. This appears to be the instant case and the claims are not commensurate in scope with the specification. Applicant should note that the agents selected by the claimed method, encompass practically every known agent or compound.

8. Claims 2 and 20 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 2 is directed to methods using fragments or homologues of FAK2. Claim 20 is a dependent claim. The claims do not require that the recited fragments and homologues possess any particular conserved structure or other disclosed distinguishing feature. Thus, the claims recite a genus of molecules, which are fragments and homologues of FAK2 protein, that are defined only by structural similarity. However, the instant specification fails to describe the

entire genus of proteins, which are encompassed by these claims. In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant has possession of a protein FAK2 of a specific known amino acid sequence. The claims, however, are drawn to methods of using fragments and homologues of FAK2. Thus, the claims are not limited to the use of a protein with a specific amino acid sequence. The claims only require that the claimed method uses proteins with some degree of structural similarity to the known FAK2 protein. The specification only describes FAK2 and fails to teach or describe any other protein which lacks the disclosed structure and retains the activities possessed by FAK2.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the recited product, or any combination thereof. In this case, the only factor present in the claim is a partial structure and no identification of any particular portion of the structure that must be conserved. As stated above, it is not even clear what region of FAK2 has the disclosed activity. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry,

whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only method of using FAK2 but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 2 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claim 2 recites the limitation "a protein that interacts with focal adhesion kinase 2" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

12. Claim 20 is indefinite for being dependent from indefinite claim.

Conclusion

13. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

February 21, 2006